IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG,	)	
Plaintiffs,	)	Civil Action No.
v.	)	
NATCO PHARMA LTD.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Novartis Pharmaceuticals Corporation and Novartis AG (collectively "Novartis"), by their attorneys, for their Complaint against Natco Pharma Ltd. ("Natco") allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, Sections 100 *et seq.* This action relates to an Abbreviated New Drug Application ("ANDA") filed by Natco with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Novartis' Gleevec® drug product.

THE PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Plaintiff Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

4. Upon information and belief, defendant Natco is an Indian company having a principal place of business at Natco House, Road No. 2, Banjara Hills, Hyderabad, Andhra Pradesh, IN - 500 034, India.

JURISDICTION AND VENUE

5. This action for patent infringement arises under 35 U.S.C. § 271.

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Upon information and belief, Natco is in the business of manufacturing, marketing, and selling pharmaceutical drug products, including generic pharmaceutical products. Upon information and belief, Natco directly, or indirectly through its affiliates and/or distributors, markets, distributes, and sells its pharmaceutical products within and throughout the United States, including in the State of Delaware and throughout this judicial district.

8. Upon information and belief, Natco established a wholly-owned Delaware subsidiary, Natco Pharma Inc., for the purpose of marketing, offering to sell and selling its generic products in the United States, including Delaware.

9. Upon information and belief, this Court has personal jurisdiction over Natco because Natco has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully availed itself of this forum, including by causing its wholly-owned subsidiary, Natco Pharma Inc., to be incorporated in Delaware and by, among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to

sell, or sell, Natco's pharmaceutical products in this judicial district, and deriving substantial revenue from such activities.

10. Upon information and belief, Natco has previously filed ANDAs and, using the process contemplated by the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), has challenged branded pharmaceutical companies' patents by filing a certification under 35 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification"), sending notice of such certification to those companies, and engaging in patent litigation arising from this process.

11. Upon information and belief, with knowledge of the Hatch-Waxman process, pursuant to 21 U.S.C. § 355(j)(2)(B)(iii) Natco directed a letter including a paragraph IV certification to Novartis, including NPC which is a Delaware corporation, and deliberately challenged Novartis' patent rights, knowing that such certification could trigger a patent infringement suit from Novartis under the Hatch-Waxman Act. Moreover, upon information and belief, Natco knew that other Hatch-Waxman infringement actions relating to the same patents had been brought and litigated in Delaware.

12. Upon information and belief, this Court has personal jurisdiction over Natco because Natco has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to NPC, a Delaware corporation, such that Natco should anticipate being haled into court in this judicial district.

13. Upon information and belief, this Court also has personal jurisdiction over Natco under Federal Rule of Civil Procedure 4(k)(2).

14. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) & (c) and 1400(b).

THE PATENTS IN SUIT

15. United States Patent No. 6,894,051 (the "'051 Patent") duly and legally issued on May 17, 2005 to inventors Jürg Zimmermann, *et al*. A true and correct copy of the '051 Patent is attached hereto as Exhibit A.

16. The '051 Patent is assigned to Novartis AG, and NPC is an exclusive licensee under the '051 Patent.

17. United States Reissue Patent No. RE43,932 (the "RE932 Patent") duly and legally issued on January 15, 2013 to inventors Jürg Zimmermann, *et al*. A true and correct copy of the RE932 Patent is attached hereto as Exhibit B.

18. The RE932 Patent is assigned to Novartis AG, and NPC is an exclusive licensee under the RE932 Patent.

ACTS GIVING RISE TO THIS ACTION

19. Plaintiff NPC holds an approved New Drug Application ("NDA") No. 21588 for Gleevec® tablets containing 100 mg and 400 mg imatinib mesylate, which was approved by the FDA on April 18, 2003.

20. By letter dated September 15, 2015 ("Natco's Notice Letter"), Natco notified Novartis that it had submitted ANDA No. 207818 to the FDA under Section 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, offer to sell or sale of tablets containing 100 mg and 400 mg of imatinib mesylate (the "Imatinib Mesylate ANDA Tablets"). Upon information and belief,

Natco stated in its ANDA that its Imatinib Mesylate ANDA Tablets are bioequivalent to Novartis' 100 mg and 400 mg imatinib mesylate Gleevec® tablets.

21. As stated in its Notice Letter, Natco's ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, use and/or sale of Natco's Imatinib Mesylate ANDA Tablets prior to the expiration of the '051 Patent and the RE932 Patent which are listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book") as being applicable to Novartis' Gleevec® tablets. On information and belief, Natco intends to engage in the commercial manufacture, use and/or sale of Natco's ANDA Imatinib Mesylate Tablets promptly upon receiving FDA approval to do so.

22. In its Notice Letter, Natco notified Novartis that its ANDA contained a "paragraph IV certification" that in Natco's opinion, the '051 Patent and the RE932 Patent are invalid, unenforceable or will not be infringed by the manufacture, use, sale, or offer to sell of Natco's Imatinib Mesylate ANDA Tablets.

23. Natco's filing of its ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell or sale of its Imatinib Mesylate ANDA Tablets, prior to the expiration of the '051 Patent and the RE932 Patent, constitutes infringement of one or more of the claims of those patents under 35 U.S.C. § 271(e)(2).

24. Natco's commercial manufacture, use, offer to sell or sale of Natco's Imatinib Mesylate ANDA Tablets, prior to the expiration of the '051 Patent and the RE932 Patent, would constitute infringement of the '051 Patent and the RE932 Patent under 35 U.S.C. § 271.

25. Upon FDA approval of Natco's ANDA, Natco will infringe the '051 Patent and the RE932 Patent by making, using, offering to sell, and/or selling Natco's Imatinib Mesylate ANDA Tablets in the United States unless enjoined by this Court.

26. Natco had notice of the '051 Patent and the RE932 Patent at the time of its infringement.

27. Novartis will be substantially and irreparably damaged and harmed if Natco's infringement is not enjoined. Novartis does not have an adequate remedy at law.

WHEREFORE, Novartis respectfully requests the following relief:

(a) a judgment and decree that the '051 Patent and the RE932 Patent are valid and enforceable;

(b) a judgment and decree that Natco has infringed one or more claims of the '051 Patent and the RE932 Patent in violation of 35 U.S.C. § 271;

(c) a judgment declaring that Natco's making, using, selling, offering to sell or importing Natco's Imatinib Mesylate ANDA Tablets will infringe the '051 Patent and the RE932 Patent;

(d) a judgment providing that the effective date of any FDA approval for Natco to make, use or sell Natco's Imatinib Mesylate ANDA Tablets be no earlier than the date on which last-expiring patent of the '051 Patent and the RE932 Patent expires, including any associated regulatory exclusivities;

(e) a judgment permanently enjoining Natco from making, using, selling, offering to sell, or importing Natco's Imatinib Mesylate ANDA Tablets until after expiration of the '051 Patent and the RE932 Patent, including any associated regulatory exclusivities;

(f) if Natco engages in the commercial manufacture, use or sale of Natco's Imatinib Mesylate ANDA Tablets prior to the expiration of the '051 Patent and the RE932 Patent, a judgment awarding Novartis damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(g) a judgment awarding Novartis attorneys' fees in this action pursuant to 35 U.S.C. § 285;

(h) a judgment awarding Novartis costs and expenses in this action; and

(i) a judgment awarding Novartis such further and other relief as this Court may deem just and proper.

Dated: October 28, 2015

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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